

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
CINCINNATI DIVISION**

PATRICK and STEPHANIE DE GARAY,

Plaintiffs,

-against-

HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No.

COMPLAINT

Plaintiffs Patrick and Stephanie de Garay bring this action against Defendant U.S. Department of Health and Human Services to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 (“**FOIA**”). As grounds therefor, Plaintiffs allege as follows:

JURISDICTION AND VENUE

1. The Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.
2. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) since Plaintiffs reside in this District and Division.

PARTIES

3. Plaintiffs Stephanie and Patrick de Garay are the parents of M.D., a participant in Pfizer’s COVID-19 vaccine clinical trial for 12- to 15-year-olds. (**Exhibit A.**)
4. Defendant U.S. Department of Health and Human Services (“**HHS**”) is an agency of the U.S. Government headquartered at 200 Independence Avenue, SW, Washington, DC 20201. HHS has possession, custody, and control of records to which Plaintiffs seek access.

STATEMENT OF FACTS

5. On June 1, 2022, Plaintiffs sent a FOIA request (“**FOIA Request**”) to the Food and Drug Administration (“**FDA**”), an agency of the Defendant HHS via online portal, seeking access to the following:

Each and every email communication between December 30, 2020 and the date of search sent or received by Janet Woodcock, Stephen Hahn, Peter Marks, Marion Gruber, Philip Krause, Paul Richards, and/or Lorrie McNeill that includes the words (“[redacted]” or “[redacted]”) and (“deGaray” or “de Garay”) in the body, subject line, or any other part of the email.

See attached declaration and corresponding documents regarding the waiver of privacy rights and consent to release responsive records. [Exhibit A.1.]

(Exhibit A.)

6. By letter dated June 3, 2022, FDA acknowledged receipt of the request and assigned Plaintiffs FOIA Control #2022-4101. **(Exhibit B.)**

7. In addition to acknowledging receipt, the FDA’s June 3, 2022 letter forecasted a possible inability for the agency to abide by FOIA’s time limits. Specifically, the letter stated:

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved.

8. On July 16, 2022, Plaintiffs’ counsel sent FDA a request for an estimated date of completion for the FOIA Request, pursuant to 5 U.S.C. 552 (a)(7)(B)(ii). **(Exhibit C.)**

9. On July 21, 2022, FDA's Director of its FOIA Division, Sarah B. Kotler, responded to the estimated completion date request via email, and stated: "2022-4101: 18-24 months CBER."
(Exhibit D.)

10. As of the date of this Complaint, Defendant HHS has failed to: (i) determine whether to comply with the request; (ii) notify Plaintiffs of any such determination or the reasons therefor; (iii) advise Plaintiffs of the right to appeal any adverse determination; or (iv) produce the requested records or otherwise demonstrate that the requested records are exempt from production.

COUNT I
(Violation of FOIA, 5 U.S.C. § 552)

11. Plaintiffs realleges paragraphs 1 through 10 as if fully stated herein.

12. Defendant HHS is in violation of FOIA.

13. Plaintiffs are being irreparably harmed by reason of Defendant HHS's violation of FOIA, and Plaintiffs will continue to be irreparably harmed unless Defendant HHS is compelled to comply with the law.

14. Plaintiffs have no adequate remedy at law.

15. To trigger FOIA's administrative exhaustion requirement, Defendant HHS was required to make a final determination on Plaintiffs' request by July 5, 2022. However, because Defendant HHS failed to make a final determination on Plaintiffs' request within the time limits set by FOIA, Plaintiffs are deemed to have exhausted their administrative appeal remedies.

WHEREFORE, Plaintiffs respectfully request that the Court: (1) order Defendant HHS to conduct searches for any and all records responsive to Plaintiffs' FOIA request and demonstrate that it employed search methods reasonably likely to lead to the discovery of records responsive to Plaintiffs' FOIA request; (2) order Defendant HHS to produce, by a date certain, any and all

non- exempt records responsive to Plaintiffs' FOIA request and a *Vaughn* index of any responsive records withheld under claim of exemption; (3) enjoin Defendant HHS from continuing to withhold any and all non-exempt records responsive to Plaintiffs' FOIA request; (4) grant Plaintiffs an award of attorneys' fees and other litigation costs reasonably incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and (5) grant Plaintiffs such other relief as the Court deems just and proper.

Dated: September 2, 2022

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